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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,112

07/07/2004

Robert J Benkowski

0021906.023US

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03/19/2009

LOCKE LORD BISSELL & LIDDELL LLP

ATTN: IP DOCKETING

600 TRAVIS

SUITE 3400

HOUSTON, TX 77002-3095

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

03/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hoip@lockelord.com

Office Action Summary	Application No. 10/501,112	Applicant(s) BENKOWSKI ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 19, 20 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19, 20, 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/09 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 19, 20, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of “pump” in regards to the diastolic flow rate and mean flow rate is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification states on page 6, line 15 to page 7, line 16 that the “patient's diastolic VAD flow rate” is monitored and used to increase the pump speed and references the diastolic “pump” flow rate and mean “pump” flow rate and not just the use of “diastolic flow rate” or “mean flow rate” without the “pump”/VAD.

Claims 1-15, 19, 20, and 24-28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter not described in the original specification is the use of the “diastolic flow rate” and “mean flow rate” instead of the disclosure’s description of the diastolic “pump” flow rate or mean “pump” flow rate. This new limitation of “diastolic flow rate” or “mean flow rate” represent a different range than what was originally presented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, the claim is incomplete for omitting connection to the rest of the device of claim 7. The claim is just a listing of parts.

In claim 20, “may be use” is vague since it does not specifically state it is used to perform that function. If it may be used does it also mean that it may not be used for that function?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-15, 19, and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et al (2004/0152944). Medvedev discloses that the pump speed is changed based on or in response to the diastolic flow rate (e.g. paragraphs 57-61, DQ) and based on the heart rate or pressure (e.g. abstract). In addition, the pump speed is set in accordance with activities, such as sleep, normal activity, or high-energy activity, since the heart rate or other sensed parameters will change in response to these activities affecting the speed of the pump. For claim 19, the system senses pressure through the three feedback waveforms and for claim 8, the system of Medvedev includes an implantable flow measurement device since implantable device measures flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Medvedev et al. Medvedev discloses the claimed invention except for sensing of diastolic flow rate from the sensed pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pump and method as taught by Medvedev, with the sensing of diastolic flow rate from the sensed pressure since it was known in the art/the examiner is taking official notice that implantable pumps and methods use the sensed pressure to determine diastolic flow rate to provide the predictable results of a conventional way to easily determine the flow rate from sensed pressure without using other flow sensors.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The arguments/statements "In light of *Hakim v. Canon Avent Group PLC*, 479 F.3d 313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007), Assignee retracts and expressly disavows all arguments made in all related pending and expired applications" and "In light of the mootness of the previous rejections, Assignee hereby expressly retracts its previous arguments with respect to the previously presented claims in accordance with *Hakim v. Canon Avent Group PLC*, 479 F.3d 313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007)" have NOT been accepted. The examiner has based his examination of this application on the claims, disclosure, and previous arguments made by the Applicant. If the Applicant wishes to specifically point out what arguments are incorrect and why, the Examiner will review those specific arguments, but a blanket statement that all arguments have been retracted/disavowed will not be accepted. If all arguments from the past year and a half are to be

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disavowed/retracted, it is unclear why the Examiner would be convinced or persuaded by future arguments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

George R Evanisko
Primary Examiner
Art Unit 3762

GRE
3/13/09